

REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and these comments.

Claim 26 is amended currently. Upon entry of this response, which introduces no impermissible new matter, claims 1-33 will be pending and claims 1-25 and 31-33 will be withdrawn.

Claim Rejections under 35 U.S.C. § 102

Claims 26-30 were rejected for alleged anticipation by U.S. patent No. 4,916,056 ("Brown"). Without acquiescing to the rejection, applicant has revised independent claim 26. Further, applicant traverses the rejection for the reasons set forth below.

Claim 26 is directed to a "flow-through assay apparatus for detecting an analyte" which comprises "(A) a solid-phase support onto which a capture reagent that specifically binds to the analyte has been immobilized and (B) a porous material impregnated with a labeled reagent containing a ligand that specifically binds to the analyte." As recited, the "porous material is contained in an adaptor that (i) is provided in an upper layer of the solid-phase support and (ii) is contacted with the solid-phase support." Furthermore, "the porous material is configured such that (iii) the analyte and the labeled reagent are contacted and mixed within the porous material and (iv) the porous material does not block the opening of the adaptor, whereby aggregated images are observable without removing the adaptor" (emphasis added).

As claim 26 thus prescribes, the adaptor provided in an upper layer of the solid-phase support is in contact with the solid-phase support and the porous material is configured such that the analyte and the labeled reagent are contacted and mixed within the porous material. Further, the porous material is configured such that it does not block the opening of the adaptor. Pursuant to claim 26, therefore, the porous material is supplied so as to allow for observation of aggregated images without removal of the adaptor.

Brown discloses a flow-through assay device comprising the porous prefilter 22d and the reaction matrix 12. However, Brown does not teach that the porous material of the device, *i.e.*, the porous prefilter 22d, is supplied in a manner such that it does not block the opening of the adaptor (see FIGS 1, 2 and 5, where the base of the filter means 22 is defined by the porous prefilter 22d), such that aggregated images can be observed without removing the adaptor. Instead, Brown discloses a filtering means 22 disposed over a reaction site or surface 12a of the reaction matrix 12.

Accordingly, the presently claimed flow-through assay apparatus and Brown's flow-through assay device differ both in structure and in function. Applicant therefore requests withdrawal of the rejection of claim 26 and its dependents, claims 27-30. Conversely, should this rejection be maintained then the examiner is requested to point out with specificity where Brown teaches the above-mentioned features.

Claim Rejections-35 USC§103

Claims 26-30 were rejected over WO 03/016902 ("Cole 1") in view of U.S. patent No. 5,141,850 ("Cole 2"). Again, without acquiescing to the rejection applicant has amended claim 26. Further, applicant traverses the rejection for the reasons set forth below.

The characterization above of claim 26 is incorporated here by reference. As previously noted, the porous material in the flow-through assay apparatus of claim 26 is supplied in a manner such that the porous material does not block the opening of the adaptor. This arrangement permits observation of aggregated images without removal of the adaptor, which in turn allows for quick detection of an analyte.

Cole 1 discloses a flow-through apparatus comprising a first member comprising a first, porous, reaction membrane. A capture analyte for binding to a reagent, is bound to the reaction membrane. The flow-through apparatus further comprises a chamber spaced above the first member, having side walls and a base defined by a second membrane (see Figure 1). Cole 1 also discloses that a sample and labeled reagent are added to the chamber and allowed to flow through to the reaction chamber. Cole 2 teaches that the labeled reagent may be immobilized in a porous material.

On the other hand, Cole 1 does not disclose or even suggest configuring the porous material, *i.e.*, the membrane 22, such that it does not block the opening of the adaptor (see FIGS 1 and 2, the base of the chamber 21 is defined by the membrane 22) and aggregated images can be observed without removing the adaptor. Instead, as shown in Figs. 1 and 2, Cole discloses a membrane 22 provided across a filter unit frame 14. Additionally, Cole 2 fails to cure the deficiencies of Cole 1.

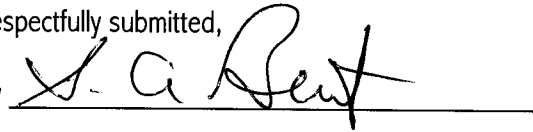
Accordingly, the combination of Cole 1 and Cole 2 fail to disclose the structure of the flow-through assay apparatus of claim 26. Since this deficiency defeats the alleged *prima facie* case, applicant respectfully requests withdrawal of the rejection against claim 26 and dependent claims 27-30. Conversely, should this rejection be maintained then the examiner is requested to point out where in the cited combination the above-mentioned features are found.

CONCLUSION

Applicant submits that this application is in condition for allowance, and an early indication to this effect is requested. Examiner Nguyen also is invited to contact the undersigned directly, should he feel that any issue warrants further consideration.

Respectfully submitted,

By



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FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5404
Facsimile: (202) 672-5399

Stephen A. Bent
Attorney for Applicant
Registration No. 29,768

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